Office Action Summary	Application No.	Applicant(s)	
	10/531,463	MORIYA ET AL.	
	Examiner	Art Unit	
	Layla Bland	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/1/2007, 4/15/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a national stage entry of PCT/JP04/02780, filed March 4, 2004, and claims priority to Japanese applications 2003-061382 filed March 7, 2003, 2003-061379 filed March 7, 2003 and 2004-028965 filed February 4, 2004. Claims 1-3 and 6-8 are pending in this application and are examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagon et al. (JP 2003-040785, February 13, 2003, machine translation) in view of Japan Food Additive Association (http://www.aureo.co.jp/english/glucan/glucan6.html, table from Explanatory Notes for Products in Existing Food Additives List, published 1999).

Wagon et al. teach a composition containing β-glucan and heat-treated lactic acid producing bacteria, preferably *Enterococcus faecalis* [see abstract]. The amount of the β-glucan-containing material is 0.5-99.5% by weight and the lactic acid producing bacteria 99.5-0.5 percent by weight [see abstract]; or more preferably, 10-90% and 90-

10% by weight [0032]. The β-glucan is preferably derived from basidomycete, yeast, bacteria, algae and lichen [see abstract and claim 3].

The source of the glucan is not given patentable weight; merely the β-1,3-1,6-glucan itself is considered. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

The limitations "constipation-relieving drug", "immunopotentiator," and "skin moisturizer," as in claims 6-8, are considered intended use or inherent properties of the composition which are not given patentable weight; thus the claims are considered drawn to the composition only.

Wagon et al. do not exemplify a composition comprising β-1,3-1,6-glucan.

Japan Food Additive Association teaches that β-1,3-1,6-glucan is obtained from Aureobasidium pullulans, is known to activate the immune system, is a health food, and can be used in drinks, sauces, bread, and other foods [table].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising β-1,3-1,6-glucan and dead lactic acid bacterium *Enterococcus faecalis* cells. Wagon et al. teach a composition comprising β-glucan and the aforementioned dead bacterium cells and also teach that the β-glucan can be obtained from yeast. The skilled artisan would have been motivated to use β-1,3/1,6 glucan obtained from Aureobasidium pullulans because Japan Food Additive Association teaches that it is known to activate the immune system. The skilled artisan would have had a reasonable expectation of success because Japan Food Additive Association teaches that β-1,3/1,6 glucan is already in use as a health food.

Claims 1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keiichiro (JP 2001-048796, February 2, 2002, abstract, PTO-1449 submitted April 14, 2006) and Japan Food Additive Association (http://www.aureo.co.jp/english/glucan/glucan6.html, table from Explanatory Notes for Products in Existing Food Additives List, published 1999).

Keiichiro teaches an imunomodulator containing the killed cells of *Enterococcus faecalis* [abstract].

Japan Food Additive Association teaches as set forth above, that β-1,3/1,6 glucan obtained from Aureobasidium pullulan activates the immune system and can be used in a variety of foods [table].

Neither Keiichiro nor Japan Food Additive Association teaches a composition comprising both killed cells of *Enterococcus faecalis and* β-1,3/1,6 glucan.

The source of the glucan is not given patentable weight; merely the β-1,3-1,6-glucan itself is considered. The limitations "constipation-relieving drug", "immunopotentiator," and "skin moisturizer," as in claims 6-8, are considered intended use or inherent properties of the composition which are not given patentable weight; thus the claims are considered drawn to the composition only.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising both killed cells of *Enterococcus faecalis and* β-1,3/1,6 glucan. The prior art teaches both elements and teaches that each is useful as an immunomodulator. One of ordinary skill in the art could have predicted that the combination of two immunomodulators would also be useful as an immunomodulator.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

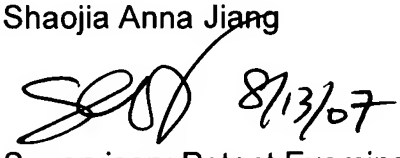
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
August 7, 2007

Shaojia Anna Jiang



Supervisory Patent Examiner
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August 7, 2007